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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/758,864 | 01/16/2004 | Erik H.F. Wong | 30744/6248.11 | 1198 |

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| EXAMINER | |
|---|---|
| SPIVACK, PHYLLIS G | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/758,864 | WONG ET AL. | |
| | Examiner | Art Unit | |
| | Phyllis G. Spivack | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12,14-17,39,40 and 54-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-17,39,40 and 54-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed January 17, 2006 is acknowledged. Claims 13 and 32-38 are now canceled. New claims 54-67 are presented. Accordingly, claims 1-12, 14-17, 39, 40 and 54-67 are presently under consideration.

A new title, updated priority information and an amended Abstract are noted.

An Information Disclosure Statement filed February 10, 2006 is further acknowledged and has been reviewed to the extent each reference is a proper citation on a U.S. patent.

A Declaration of Stephen P. Arneric pursuant to 37 CFR 1.132 and a "Statutory Declaration" of Dr. Sian Louise Ratcliffe, both filed January 17, 2006, are further acknowledged.

In the last Office Action all claims were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims are directed to the treatment of peripheral neuropathy, broadly considered to be diseases of the peripheral nervous system that are characterized by inflammation, pain, paralysis and/or muscle wasting, optionally, while diminishing adverse side effects. It was asserted the specification provides a review of various pathologies that are known in the prior art to respond to treatment with reboxetine and provides support for the ability of racemic or enantiomeric reboxetine to bind to norepinephrine and serotonin reuptake sites using two radioligands. There is no support for treating peripheral neuropathy and, optionally, diminishing adverse side effects.

The Arneric Declaration demonstrates inhibition constants of compounds for various monoamine transporters and receptors and the selectivity for the norepinephrine transporter over the serotonin transporter.

The Declaration is not commensurate in scope with the present claims in that it fails to provide support for the administration of S,S-reboxetine to treat peripheral neuropathy, optionally, while diminishing adverse side effects.

Dr. Ratcliffe' Declaration refers to a patient population having post-herpetic neuralgia, an example of peripheral neuropathy, who received either racemic reboxetine and (S,S) reboxetine. In the population receiving (S,S) reboxetine less adverse side effects, such as palpitations, tachycardia, dry mouth, hyperhidrosis and anorexia were clearly noted.

However, peripheral neuropathy results from genetic or idiopathic disorders, viral or microbial diseases other than herpes, as hepatitis, mononucleosis or diphtheria; porphyric, toxic or organic substance-induced, such as carbon monoxide; metal-induced, as arsenic, mercury, lead or antimony; or carcinoma. See Table 331-1 on page 1806, Harrison's Principles of Internal Medicine, which is provided only as background material to show the breadth of "peripheral neuropathy".

While the limitation in claim 39, "while diminishing adverse side effects" during (S,S) reboxetine administration is supported by the Ratcliffe Declaration, the claims are drawn to subject matter that is far broader than the patient population having post-herpetic neuralgia.

The rejection of record under 35 U.S.C. 112, first paragraph, is maintained over claims 1-12, 14-17, 39 and 40. The rejection is extended to include new claims 54-67.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 14-17, 39, 40 and 54-67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,465,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because according to the Ratcliffe Declaration, the patient population having post-herpetic neuralgia, an example of peripheral neuropathy, experienced chronic neuropathic pain.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

March 30, 2006

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER